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VIA UPS OVERNIGHT

June 24 , 2005

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

The undersigned submit this petition under Section 201, 403, and 701 (21 U.S.C. 321, 343 and 371) of the Federal Food, Drug and Cosmetic Act to request the Commissioner of Food and Drugs to amend 21 C.F.R. §101.12(b) Table 2 Reference Amount Customarily Consumed Per Eating Occasion: General Food Supply, by establishing a separate reference amount for fruitcake of 43 grams (1½ ounces).

A. Action Requested

Petitioners request that Table 2 of 21 C.F.R. §101.12(b) be amended as set forth below.

Table 2 provides, in relevant part:

Product Category	Reference Amount	Label Statement
Cakes, heavy weight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combined)	125 g	__ piece(s) (__ g) for distinct pieces (e.g., sliced or individually packaged products); __ fractional slice (__ g) for large discrete units

Petitioners request the table be amended to read as follows:

Product Category	Reference Amount	Label Statement
Cakes, heavy weight (cheese cake; pineapple upside-down cake; nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as nuts, or vegetables or any of these combined)	125 g	__ piece(s) (__ g) for distinct pieces (e.g., sliced or individually packaged products); __ fractional slice (__ g) for large discrete units
Fruitcakes	43 g.....	__ piece(s) (__ g) for distinct pieces (e.g., sliced or individually packaged products); __ fractional slice (__ g) for large discrete units

B. Statement of Grounds

A majority of the members of the fruitcake manufacturing industry respectfully petition the agency to amend the reference amount of 125 grams for fruitcake (included in the category "heavy cakes" set forth in 21 C.F.R. §101.12(b)). This petition is filed on behalf of the following companies who manufacture approximately 75% of the fruitcakes sold in the United States: We know of no member of the industry who disagrees with this proposal.

W. Dale Parker
Claxton Bakery
203 West Main Street
Claxton, Georgia 30417
(912) 739-3441

Robert McNutt, President
Collin Street Bakery
401 West Seventh Avenue
Corsicana, Texas 75110
(903) 654-6620

Ronald Young, Sr.
Grandma's Bake Shoppe
201 South 5th Street
P.O. Box 457
Beatrice, Nebraska 68310
(800) 228-4030

Geoffrey J. Crowley, President
M. K. Commercial Kitchens, Inc.
dba The Ya-Hoo! Baking Co.
5302 Texoma Parkway
Sherman, Texas 75090

This petition will address each subparagraph of 21 C.F.R. §101.12(h), but an introduction is necessary to demonstrate the inaccuracy of the current serving size of 125 grams.

INTRODUCTION

The establishment by the agency of reference amounts from which serving sizes are obtained for the thousands of foods consumed by Americans was a gargantuan undertaking. The agency performed a most valuable public service in carrying out its statutory obligation. Very few changes in the regulations have been sought or granted, a clear demonstration of the agency's expertise and diligence. With respect to the reference amount for fruitcake, however, we submit that the agency's decision was based on totally inadequate data. The fruitcake industry is at fault for not pointing out this defect at the time the regulation was proposed, but that is all water over the dam and we respectfully request the agency to amend the reference amount to 43 grams (1½ ounces), the serving size customarily used by the industry for decades, and recognized in at least one USDA publication.

On May 6, 2005, Geoffrey J. Crowley, President of M. K. Commercial Kitchens, Inc., dba The Ya-Hoo! Baking Co., summarized the industry position in a letter to counsel:

Our labels comply with the present FDA standards and guidelines regarding proper labeling and specifically serving size. We believe that the FDA serving size does not in actuality conform to customary consumption practice because the richness of the product causes it to be normally consumed in 1 oz to 1.5 oz portions. The expense of the product is also a factor, since the current FDA serving size guideline calls for a portion costing over \$3.00, typically. Customarily, our 14 oz loaf will serve 10 generous slices. I have never observed anyone actually eating 1/3 of that cake in one sitting, as called for by the present government guideline, nor would we ever suggest for anyone to do so, as we would consider that to be over-indulgent and probably unhealthy.

For over 25 years we have sold several fruitcake items that are pre-portioned and or sliced and individually wrapped. Examples include fruitcake cupcakes "miniatures" and "sliced and wrapped" fruitcake. In no case does the portion size exceed 1.8 oz and most are less than 1.5 oz.

Fruitcake is primarily a traditional and seasonal product, usually thought of as a delicacy, to be enjoyed in moderation. In summary, we submit that the present government guidelines, that require abnormally large portions, is contrary to customary and nutritionally advisable practice. (Attachment 1)

To assist in reviewing and analyzing the data on which FDA's fruitcake reference amount decision was made, we consulted Dr. Barbara Petersen, an expert in this field, formerly associated with Novigen which was acquired by Exponent, Inc. Dr. Petersen's curriculum vitae is Attachment 2, and her report is Attachment 3. To summarize the report, Exponent:

1. Reviewed the information that FDA used to define the reference amount for heavy cakes (the category that includes fruitcakes);
2. Reviewed related data available in the USDA's National Nutrient Database regarding the serving size for fruitcake.

The agency established three categories for "cakes," heavy weight (125 grams), medium weight (80 grams), and light weight (55 grams). These values were primarily based on FDA's

analysis of the USDA's Nationwide Food Consumption Surveys from 1977-1978 and 1987-1988. Dr. Petersen reports that only 19 consumers were included in the fruitcake serving size decision.

In responding to the USDA survey, many consumers of fruitcake did not estimate their serving size amount and their consumption was estimated by FDA by assigning a "default" value as noted in Appendix 1 to the USDA survey (Attachment 4). "USDA Default Serving Sizes" were used when the respondents could not specify a serving size. This resulted in default serving sizes for about 75 different kinds of cakes. One of these, 531-10000 is "cake, fruitcake, light/dark, holiday type cake." The default serving size is 113 grams.

FDA has also had available the 1994-1996 and 1998, USDA Continuing Survey of Food Intakes by Individuals (CSFII). This survey apparently included only 15 consumers of fruitcake, so it too is deficient. Among those 15, the mean serving size is 91.3, the median 107.3 and the 90th percentile 144.2 grams.

Dr. Youngmee K. Park of the Clinical Nutrition Branch of CFSAN issued a very comprehensive memorandum on October 30, 1991 on the subject of "Documentation For Determining Reference Amounts Customarily Consumed Per Eating Occasion." On pages 11 and 12, Dr. Park explains that the adequacy of sample size was classified into three categories: adequate, intermediate and inadequate. If a sample size consisted of 140 or more eating occasions, the agency considered it to be "adequate". If the sample size consisted of 40 to 139, the agency classified it as "intermediate" and added that it "may not be large enough to provide reasonable assurance of a reliable estimate of the customarily consumed amount considering the multiple modes observed for many product categories."

If the sample size consisted of less than 40, the agency considered it to be “inadequate to provide reasonable assurance of a reliable estimate of the customarily consumed amount.” The 1977–1978 and 1987–1988 surveys included only 19 consumers, less than half the amount considered to be “inadequate.” The 1994–1996 and 1998 surveys included only 15 consumers of fruitcake, also less than half of the number required to graduate from the “inadequate” to the “intermediate” category. Even adding the 19 and 15 together (which is statistically not acceptable) the total is only 34, still less than the 40 required to escape the “inadequate” category. (Attachment 5, only the relevant pages are included in this attachment.)

We have been unable to determine the source or rationale for the establishment of 125 grams serving size for fruitcake, but 125 grams happens to be half way between the median and the 90th percentile. We submit that this is not an appropriate basis for establishing a reference amount. Surely 15 or 19 as in the 1977–1978 and 1987–88 surveys, is a statistically and logically invalid and inadequate basis for establishing a reference amount unless no other data are available. Since the surveys were apparently all the agency had to consider, and since the industry did not come forth with anything different, the 125 grams in the default serving size for cakes in the “cakes, heavy weight” category was apparently used. As far as the petitioners can determine, this had absolutely nothing to do with the customary serving size for fruitcakes and may have been based on consumption of other types of cakes, or possibly on a simple mathematical calculation. Hence, this petition.

**BASIS FOR THIS PETITION TO AMEND
THE SERVING SIZE FOR FRUITCAKE**

21 C.F.R. §101.12(h) authorizes the Commissioner to amend a serving size pursuant to a petition which must set forth the basis for the petitioner's request for an amendment. The balance of this petition will follow the subparagraphs in 21 C.F.R. §101.12(h).

(1) Objective of the Petition

The objective of the petition is to establish a reasonable category for fruitcakes supported by appropriate data.

(2) A Description of the Product

Section 201(f) of the Federal Food, Drug, and Cosmetic Act provides that the term food means "(1) articles used for food or drink for man or other animals." 21 U.S.C. 321(f). In other words, food is food. Fruitcake is such a commonly recognized article of trade in the United States that the agency should simply follow the precedent set by Congress, and describe fruitcake as the food commonly known as fruitcake. The petitioners have slight differences in formulas among their products, but all of the products are recognized by all of the industry and consumers as "fruitcake." Fruitcake is such a commonly recognized and well-established food that out of all 175 or so cakes listed in Appendix 1 in CSFII, it is probably the one that least requires further definition. Gertrude Stein would say "a fruitcake is a fruitcake is a fruitcake!" As Dr. Petersen says on page 5 of her report:

Although Fruitcake contains the word "cake" it is more like a confectionary product and it is sufficiently different from all other baked goods that it should be given a separate "reference value."

(3) *A Complete Sample Product Label Including Nutrition Label, Using the Format Established by Regulation*

Among the attachments are examples of product labels currently used by the petitioners. Please note that some of the labels include a voluntary second column of nutrition information as authorized by 21 C.F.R. §101.9(b)(10)(i). This section is cited in several letters from the agency (Attachments 6a-d). These letters are an implicit admission that the agency is not comfortable with the 125 gram serving size.

(4) *A Description of the Form (e.g., Dry Mix, Frozen Dough) in Which the Product Will be Marketed*

Fruitcakes will be marketed in a ready-to-eat form as they customarily have been for decades.

(5) *The Intended Dietary Uses of the Product with the Major use Identified (e.g. Milk as a Beverage and Chips as a Snack).*

Fruitcake is a historically well-established food consumed as such.

(6) *If the Intended Use is Primarily as an Ingredient in Other Foods, List of Foods and Food Categories in Which the Product will be Used as an Ingredient with Information on the Prioritization of the Use.*

Not Applicable

(7) *The Population group for Which the Product will be Offered for use (e.g., Infants, Children under 4 Years of Age).*

Fruitcake is consumed by all populations, but rarely by infants.

(8) *The Names of the Most Closely Related Products (Or In the Case of Foods for Special Dietary Use and Imitation or Substitute Foods, the Names of the Products for Which They are Offered as Substitutes)*

No products are “closely related” to fruitcake. They are *sui generis* and for decades have been recognized by all population groups in the United States.

(9) The Suggested Reference Amount (the Amount of Edible Portion of Food as Consumed, Excluding Bone, Seed, Shell, or Other Inedible Components) for the Population Group for Which the Product is Intended with Full Description of the Methodology and Procedures that were used to Determine the Suggested Reference Amount. In Determining the Reference Amount, General Principles and Factors in Paragraph (a) of this Section should be Followed.

The USDA and FDA survey data are insufficient to establish an appropriate reference amount for fruitcake. In describing the general principles and factors that FDA considered in arriving at reference amounts, 21 C.F.R. §101.12(a), states that:

(5) When survey data were insufficient, FDA took various other sources of information on serving sizes of food into consideration. These other sources of information included:

- (i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;
- (ii) Serving sizes recommended in comments;
- (iii) Serving sizes used by manufacturers and grocers; and
- (iv) Serving sizes used by other countries.

Fruitcake is a classic example of a food for which “survey data were insufficient.” Since fruitcake is such a unique product, only data relating to fruitcake should be used in calculating the appropriate reference amount. Forty-three grams (or occasionally 45 grams) or 1½ ounces have been customarily used by USDA and by the industry as shown by the following Attachments:.

1. USDA reports that the serving size for one piece of fruitcake is 43 grams. USDA National Nutrient Database for Standard Reference, Release 17 (Attachment 7). See the caption on the last column which states “1.00 X 1 piece ---- 43g.”

2. Jacobs Winston Laboratories, Inc. report of analysis dated August 29, 1981 performed for Collin Street Bakery shows the serving size as "45 grams (approx. 1½ oz.)" (Attachment 8).

3. An undated document entitled "fruitcake answers" prepared by Collin Street Bakery uses 1½ ounces for both the grams of fat and the grams of carbohydrates. While the document is not dated, Collin Street Bakery believes it was produced in about the mid-1980s (Attachment 9).

4. A second "fruitcake answers" from the Collin Street Bakery file repeats these two numbers for 1½ ounces. While the document is not dated, Collin Street Bakery believes it was produced in about the late 1970s or early 1980 (Attachment 10).

5. An order form used by Grandma's Fruit Cake in 1987 lists as one product:

"D. 30-OZ. FRUIT CAKE INDIVIDUALLY SLICED and wrapped,
20 slices per cake in Gift Box and Mailing Carton."

Twenty slices in a 30 ounce fruit cake is 1½ ounces per serving (Attachment 11).

6. An order form used by Grandma's in 1990 lists as one product:

"D. 28-OZ. FRUIT CAKE INDIVIDUALLY SLICED and wrapped,
20 slices per cake in Gift Box and Mailing Carton."

Twenty slices in a 28 ounce fruit cake is 1.4 ounces per serving (Attachment 12)

7. An order form used in 1995 by Grandma's lists:

"28 Oz. Grandma's Classic Fruit & Nut Cake, 19 individual full slices/
individually wrapped/tin."

This also calculates to a 1½ ounce per serving (Attachment 13).

8. On the same form the company lists:

"28 oz. Grandma's Classic Fruit & Nut Cake, 38 individual half-slices/
individually wrapped/tin."

These half serving sizes are almost exactly ¾ of an ounce (Attachment 13).

9. Another order form which Grandma's believes was used in 2000 lists the same entries as those used in 1995 (Attachment 14).

10. Another order form used by Grandma's in 2001 shows the same two entries as the 1995 order form (Attachment 15).

11. A Grandma's advertisement used in 2003 for fruitcake uses the same numbers as the 1995 order form. (Attachment 16)

12. A current label for individual slices of Claxton Fruit Cake shows "NET WT. 1.75 OZ. (50 GRAMS)" (Attachment 17).

13. A current Collin Street Bakery label for its 1 lb. 14 oz (.85 kg) size fruitcake, (Code 10100) shows the alternative suggested serving size as "1½ oz. (43 g)." (Attachment 18).

14. A current Collin Street Bakery label for its 2 lbs. 14 oz. (1.3 kg) size fruitcake (Code 10200) shows the alternative suggested serving size as "1½ oz. (43 g)." (Attachment 19).

15. A current Collin Street Bakery label for its 4 lbs. 14 oz. (2.2 kg) size fruitcake (Code 10300) shows the alternative suggested serving size as "1½ oz. (43 g)." (Attachment 20).

16. The current catalog of M. K. Commercial Kitchens, Inc., dba. The Ya-Hoo! Baking Co. shows "individually-baked Ya-Hoo! Cakes," with 18 in each 2 lb. (32 oz.) container. Each individual piece is therefore approximately 1.77 oz. (Attachment 21, page 2)

17. In the same publication, a fruitcake of 1 lb. 12 oz. (28 oz.) contains "20 convenient portions," or 1.4 oz per serving. (Attachment 21, page 12)

18. In the same publication, a fruitcake of 1 lb. 2 oz. (18 oz.) contains “12 count” or 1.5 oz. per serving. (Attachment 21, page 13)

19. In the same publication is a fruitcake of 1 lb. 6 oz. (22 oz.) containing 15 count Minis or 1½ oz. per serving. (Attachment 21, page 13)

20. In the same publication, also on page 13, is a fruitcake of 1 lb. 2 oz. (18 oz.) containing 12 pieces, 1½ oz. per serving. (Attachment 21, page 13)

21. In the same publication on page 14 is a 1 lb. 6 oz. (22 oz.) tin of Royal Minis, 1½ oz. per serving. (Attachment 21, page 14.)

(10) The suggested reference amount shall be expressed in metric units

The suggested reference amount is 43 g.

(11) A petition to create a new subcategory of food with its own reference amount shall include the following additional information:

Not applicable.

(12) A claim for categorical exclusion under § 25.30 or 25.32

Petitioners claim a categorical exclusion under 21 C.F.R. §25.32(p).

(13) In conducting research to collect or process food consumption data

Not Applicable

(14) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act (5 U.S.C. 561).

The companies filing this petition are agreeable to engage in negotiated rulemaking but believe it is unnecessary.

C. Environmental Impact

Petitioners claim a categorical exclusion under 21 C.F.R. §25.32(p).

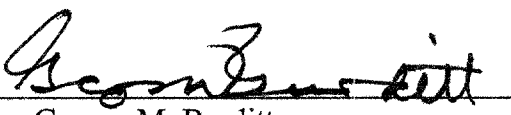
D. Economic Impact

Petitioners will submit an economic impact statement upon request of the Commissioner but believe it is unnecessary.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

BELL, BOYD & LLOYD LLC

By: 
George M. Burditt
Counsel for the Petitioners

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Attachments